Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 04-15-2011

Submission # 1

The following request has been:

- ○ Approved
- ☒ Denied

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Monday, February 28, 2011 2:10 PM
To: Gennrich, Jane - Medicaid
Subject: FW: CRESTOR (rosuvastatin calcium) - Medicaid Testimonal as requested
Attachments: IDAHO Medicaid Testimonial 2011.pdf

The presentation of this material will change, but we still will be evaluating inclusion as we have previously. So I guess we get started early.

Tami Eide, Pharm.D., BCPS
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Idaho Department of Health and Welfare
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208-364-1829
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From: Davis, Sharon [mailto:Sharon.Davis@astrazeneca.com]
Sent: Monday, February 28, 2011 9:39 AM
To: Eide, Tamara J. - Medicaid
Subject: CRESTOR (rosuvastatin calcium) - Medicaid Testimonal as requested

February 28, 2011

Tamara Eide, Pharm.D.
Idaho State Medicaid Pharmacy and Therapeutics
3232 Elder Street in Boise
Boise, ID 83705

Dear Dr. Eide:

Your Sr Regional Scientific Manager, Mandy Hosford, has forwarded your request regarding CRESTOR® (rosuvastatin calcium) Tablets. The following information is being provided, as a professional courtesy, in response to your request:

- **IDAHO Medicaid Testimonial for CRESTOR (attached)**

These materials may include information that is not found in the currently approved prescribing information. The enclosed information is intended to provide pertinent data in response to your request and should in no way be construed as a recommendation for the use of this product in any manner other than as approved by the Food and Drug Administration and as described in the prescribing information for CRESTOR. Prescription drugs used in a manner other than their approved

indication may not be eligible for reimbursement by any third-party payers, including Medicaid, Medicare, or similar federal or state programs. Prescribing information for CRESTOR may be obtained from www.astrazeneca-us.com or by calling Medical Affairs at AstraZeneca at 1-877-893-1510.

Thank you for your interest in CRESTOR. If we may be of further assistance to you, please contact AstraZeneca at 1-877-893-1510.

Sincerely,

Sharon M. Davis, Pharm.D., BCPS

Senior Medical Information Manager

CRESTOR® (rosuvastatin calcium) Medicaid Testimonial

Starting Dose:

- The usual starting dose is 10-20 mg once daily.[1]

LDL-C reductions and goal attainment:

- In the ECLIPSE and RADAR trials, CRESTOR provided superior LDL-C reductions compared to atorvastatin.[2,3]
- In the head-to-head STELLAR trial, 89% of patients receiving CRESTOR 20 mg reached their NCEP ATP III LDL-C goals.[4] CRESTOR 20 mg lowered LDL-C more than atorvastatin 20, 40 mg, simvastatin 20, 40, 80 mg, and pravastatin 20, 40 mg.[1,4]

Diabetes:

- In the ANDROMEDA trial, 96% of patients with type 2 diabetes achieved their LDL-C goal at 16 weeks with CRESTOR 20 mg, significantly more than with atorvastatin 20 mg.[5]

Jupiter Trial

- Based on the results of the JUPITER trial, CRESTOR has a primary prevention of cardiovascular disease indication.[1]
- In the JUPITER trial, 17,802 patients were randomized to either placebo or CRESTOR 20 mg and followed for a mean duration of 2 years.[1] Overall, 76% of patients had 2 or more CHD risk factors* (age plus 1 or more CHD risk factors).[6]
- Compared to placebo, CRESTOR 20 mg significantly reduced the relative risk of heart attack by 54%, stroke by 48% and arterial revascularization by 46%.[1,7]
- Based on JUPITER trial results at 4 years, the estimated number needed to treat is as follows: Treating 45 patients prevented 1 arterial revascularization, treating 95 patients prevented 1 myocardial infarction and treating 154 patients prevented 1 stroke.[8]

The following information is not within the approved Prescribing Information for CRESTOR. AstraZeneca does not recommend the use of CRESTOR in any manner other than as described in the full PI.

- In an analysis of 5,695 patients in the JUPITER trial that were ≥70 years of age, CRESTOR 20 mg significantly reduced the relative risk of major CV events by 39% compared to placebo.[9]
- In another analysis of 6801 women in the JUPITER trial, CRESTOR 20 mg significantly reduced the relative risk of major CV events by 46% compared to placebo.[10]
- In an analysis of 3,267 patients in the JUPITER trial with moderate chronic kidney disease, CRESTOR 20 mg significantly reduced the relative risk of major CV events by 45% compared to placebo.[11]

Safety Information

- In the CRESTOR controlled clinical trials database, the most commonly reported adverse reactions (incidence ≥2%) were headache, myalgia, abdominal pain, asthenia, and nausea.[1]
- Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including CRESTOR.
- Please refer to the Prescribing Information for complete product information including Warnings and Precautions.

*Not adjusted for high HDL-C (≥60 mg/dL). When this adjustment is made, the percentage of patients with 2 or more CHD risk factors at baseline was 62%.[6]

Medical Affairs Reviewed and Approved 1097100, 2/2011

Reference(s):
[1] CRESTOR Prescribing Information.
[2] Faergeman O, et al. *Cardiol.* 2008;111:219-228.
[3] Jukema JW, et al. *Curr Med Res Opin.* 2005;21:1865-1874.
[4] Jones PH, et al. for the STELLAR Study Group. *Am J Cardiol.* 2003;92:152–160.
[5] Betteridge DJ, et al. on behalf of the ANDROMEDA Study Investigators. *Diabet Med.* 2007;24:541-549.
[6] Data on File, AstraZeneca LP, DA-CRS-309408.
[7] Data on File, AstraZeneca LP, DA-CRS-295753.
[8] Data on File, AstraZeneca LP, DA-CRS-306195.
[9] Glynn RJ, et al. *Ann Intern Med.* 2010;152:488-496.
[10] Mora S, et al. *Circulation.* 2010;121(9):1069-1077.
[11] Ridker PM, et al. *J Am Coll Cardiol* 2010;55:1266–1273.